

REACH and Malaysian manufacturers

REACH is a new European Community Regulation on chemicals and their safe use. It deals with the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemical substances. The new law entered into force on 1 June 2007. The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances.

An earlier initiative 10 years ago by the EU to evaluate 150 hazardous substances failed when only 10 substances were evaluated and authorised after 10 years. Now the burden of proof is reversed and given to industry. Under REACH there are 100,204 phased-in substances and 4,381 new substances. When the White Paper was adopted in 2001 chemical manufacturers even in the EU opposed it. Later when they realized it created new business opportunities they generally supported it. That is what I believe Malaysian manufacturers should view REACH as – a business opportunity.

In the hands of bureaucrats a good intention has become quite unwieldy with documentation running into countless pages and potentially expensive. At the same time also politicised. As REACH is a European Legislation it applies only to 'actors' in EU meaning that non-European companies cannot pre-register/register substances. All this is viewed by some as a trade barrier.

What are the REACH timelines?

June 1, 2008	Beginning of pre-registration period
November 30, 2008	End of pre-registration period
November 30, 2010	Expiry of registration period for substances from 1000 metric tons per year
May 31, 2013	Expiry of registration period for 100 metric ton substances
May 31, 2018	Expiry of registration period for 1 metric ton substances

If you export to EU above 1 metric ton the last window left for you to continue to do so is between 1/6/08 to 30/11/08. If you do not pre-register it means from 1/12/08 you have to stop exporting to EU.

There was another window earlier that has now closed. A number of substances such as palm oil and palm kernel oil are not exempted whilst oils such as soya bean is. The oleochemical trade associations in ASEAN and EU have applied for such substances to be included and their application is under consideration with the results expected to be known only in December 2008.

There are exemptions but I would caution you seek expert advice in reading and understanding the regulations as these are intended to be interpreted as the regulation makers wish it to be, not what you think it means. One often quoted example is that of a ball pen whose ink needs to be registered as it is released during use. To be clear it is the substances (each more than 1 metric ton per annum) that make up the ink that have to be registered. For manufacturers of chemical substances it is clearer but for manufacturers of products closer to the end consumer expert advice is needed. That is why this article is titled REACH and Malaysian manufacturers in general, not just those who manufacture chemicals.

Only a manufacturer, importer or downstream user in the EU are 'actors'. So what can a non-EU manufacturer such as you in Malaysia do? You can

1. Use an EU importer to register your substances in his company name ie the registration does not belong to you. Or
2. If you have a legal entity in EU use it to register your substances in your company name. Or
3. Appoint an Only Representative that is a legal entity in EU to register your substances in your company name.

Bear in mind that the three entities above besides providing chemical and toxicology data on the substances have also to do the work of updating the dossier and other data such as annual import statistics so they work for you as long as you export to EU.

What are the costs? If you choose to appoint an Only Representative there may be a sign up fee. Fees increase as the deadline approaches and at this late stage figures of above Euros 20,000 are being quoted. The highest standard registration fee is Euros 31,000 per substance for an individual submission above 1000 metric tons. Then there are also management fees but this may be small in comparison to the full costs as the toxicology and eco-toxicology testing costs can be very high. It is impossible to estimate but the market speculates about Euros 300,000 per substance which cost could be shared amongst those who have pre-registered the same substance.

What should you as a Malaysian manufacturer do?

1. If you trade with EU find out if and how REACH affects your business. Sometimes you may decide it is not worthwhile to continue exporting to EU. Get expert advice now as the time for awareness is already over. It is time for action.
2. If you decide to continue exporting to EU pre-register your substances well before the 30/11/08 deadline. There is no fee for pre-registration but you need to ask your importer or your legal entity in EU or appoint an Only Representative to do the pre-registration.

What can be done for you (better late than never)?

1. Your trade association and the Ministry of International Trade and Industry set up a help desk to provide the expert advice I mentioned above. This help desk should be manned by an expert from the EU on REACH and possibly have available a list of recommended Only Representatives. I say recommended because there are no regulations on the setting up of an Only Representative office and Only Representatives do not yet have a track record.
2. Your trade association get those manufacturers with similar substances together to form a consortium to save some management and registration fees.
3. Institut Kimia Malaysia helps Malaysian laboratories to be approved in time to meet the OECD (Organisation for Economic Co-operation and Development) Principles of GLP (Good Laboratory Practice) to do the toxicology and eco-toxicology and other testing required by the registration on the basis that Malaysian costs will be lower than EU laboratories whose capacities will be largely taken up for REACH.

The above is very much simplified to get the message across so it is possible that once you go into the details the picture may change for you.

I have stated at the outset REACH is a business opportunity. There are a number of possibilities and I will give you one example. I think the deadlines will not change and I hear from an OR source that many manufacturers in a number of countries eg China are not doing anything. What will this mean for you? You could take on their market in EU but they may take you on elsewhere that does not require meeting REACH. You could also purchase their substance at a discount and export it at a premium to EU as you have a registration.

So think of REACH not as a barrier and it can open up new opportunities. Seize it now!

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